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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,766	02/18/2000	Shlomo Ben-Haim	U 014930-9	8645

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Ladas & Parry
26 West 61st Street
New York, NY 10023

EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/506,766

Applicant(s)

BEN-HAIM ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-17,19-35 and 39-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3,5-11,16,17,19-35 and 39-46 is/are allowed.
- 6) ☒ Claim(s) 12,13,15 and 47 is/are rejected.
- 7) ☒ Claim(s) 14,48 and 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The Applicant amended the independent claims to overcome the rejections of record, hence the rejections of record are withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 103

2. Claims 12, 13, 15 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US5718241) (also known as Ben-Haim et al. ('241)) in view of Goldreyer (US 5385146) and further in view of Ben-Haim et al (WO 96/05768) (also known as Ben-Haim et al. ('768)).

Ben-Haim et al. ('241) disclose a method and apparatus to treat arrhythmias with ablation using one or more catheters (abstract). The tip of the catheter contains an electrode which can function at a site in the heart to sense electrical cardiac activity, to act as an antenna to deliver radio-frequency energy to perform ablation of tissue, or to deliver stimuli for pacing the heart (col. 11 @ 28-35). The electromagnetic location system in the tip of the catheter can contain between one and ten antennas to define the location of the tip area of the catheter (col. 11 @ 49-59). In figure 16, a tip electrode (105) and additional electrodes (106) are disclosed. The receiving antennas, located near the distal tip of the catheter (col. 12 @ 41-47), provide location information for the local activation data received from the tip electrode (105) and additional electrodes (106) (col. 7 @ 15-25; col. 10 @ 33-45; claims 30 and 31).

As to generating an heart chamber electrical map, Ben-Haim et al. ('241) provide an activation map of the heart/ define the physical dimensions or anatomy of the chamber to identify electrical pathways causing arrhythmia, both fixed pathways and not anatomically fixed, superfluous electrical pathways to enable the selection of ablation sites (col. 1 @ 64 – col. 2 @ 10; col. 5 @ 21-35; col. 6 @ 39-46), hence Ben-Haim et al. teach representing multiple minimum volumes of the chamber geometry of the heart as the electrical map is generated.

As to a console, a console(86), with driver circuits and signal processor(82/84/86), is operatively connected to the at least one electromagnetic field generator (80). The receiver portion (82) of the signal processor determines location information (figure 14; col. 11 @ 49 – col. 12 @ 2).

Ben-Haim et al. ('241) disclose the claimed invention except for:

- the electrodes being non-contact electrodes linearly arranged along a longitudinal axis of the catheter body, and
- the location of the non-contact electrode determined by said at least one location sensor representing a minimum volume of the chamber of the heart .

Goldreyer discloses a catheter to sense extremely localized intracardiac electrical patterns.

As related to the non-contact electrodes arranged linearly, figures 1 and 2 disclose a catheter (10/32) including a stimulating tip (14) and non-contact electrodes (34-46) shown to be

14 electrodes, read to be about 16 electrodes (col. 5 @ 6-12). Goldreyer teaches an embodiment where the electrodes are non-contact (col. 2 @ 10-11) and are linearly arranged along a longitudinal axis of the catheter body for the purpose of sensing only signal from the myocardium directly adjacent to the electrodes (col. 1 @ 55-59). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim et al. ('241), and provide electrodes being non-contact electrode linearly arranged along a longitudinal axis of the catheter body as taught by Goldreyer to enable accurate and discrete mapping of the electrophysiologic activation within the heart (col. 1 @ 63 – col. 2 @ 4).

As related to the representation of the minimum volume of the heart chamber, Goldreyer teaches heart chamber mapping by sensing local cardiac signals in a minimal area of the heart chamber and repeating this process at predetermined positions within the chamber until accurate and discrete mapping of electrophysiologic activation within the heart is achieved (col. 1 @ 55 – col. 2 @ 11), hence the definition of the minimum volume of the heart chamber is accomplished by defining the location of the activation data within the heart chamber by a location sensor as disclosed by Ben-Haim et al. ('241) and by the predetermined position of the non-contact electrodes on the catheter as taught by Goldreyer (col. 2 @ 38-42 and 51-56; col. 3 @ 53-60). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim et al ('241), and provide the location of the non-contact electrode determined by said at least one location sensor representing a minimum volume of the chamber of the heart as taught by Goldreyer to enable accurate and discrete mapping of

electrophysiologic activation within the heart so optimal clinical treatment is provided to the patient (col. 1 @ 7-11).

As to the use of at least one location sensor on the body of the catheter for generating signals used to determine the location of an array of non-contacting electrode linearly arranged along the longitudinal axis of the body of the catheter, Ben-Haim et al. ('241) teach the use of one or more antennas (79), read as at least one location sensor (79), at the tip of the catheter, read as on the body of the catheter, for generating signals used to determine location of the tip and associated electrodes (col. 11 @ 52-57). In summary, Ben-Haim et al. ('241) teach an array of contacting electrodes (106) arranged along the longitudinal axis of the body of the catheter (figure 16) and Goldreyer teaches a catheter embodiment where the electrodes are non-contacting (col. 2 @ 10-11).

As discussed in the previous nine paragraphs of this action, modified Ben-Haim et al. ('241) disclose the claimed invention except for providing six degrees of location information using at least one locations sensor.

Ben Haim et al. ('768) disclose a position locating system and teach the use of a location sensor that provides six degrees of location information for the purpose of determining medical probe location. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method and apparatus to treat arrhythmias with ablation as taught by modified Ben-Haim ('241), providing six degrees of location information using location sensors as taught by Ben Haim et al. ('768) to enable

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accurate mapping of the heart so arrhythmia producing cardiac tissue is identified and can be ablated (page 1 @ 3-7; page 6 @ 8-12 and 22-30).

Allowable Subject Matter

3. Claims 1-3, 5-11, 16, 17, 19-35, 39-41 and 42-46 are allowed.
4. Claims 14, 48 and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Statutory Basis

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday 9 a.m. to 9 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
4/2/04



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
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